



REQUEST FOR PROPOSAL NO.: AMENDMENT NO. 02
RFP NO. NIMH-01-DS-0002

TITLE: "Data Management Support and Clinical
Trial Coordination for NIMH"

OMB No.: 0990-0115

ISSUED BY: Patricia L. Gibbons, Contracting Officer
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DATE ISSUED: Wednesday, January 10, 2001

PURCHASE AUTHORITY: Public Law 95-218 as amended

SMALL BUSINESS SET-ASIDE: Yes, 100% Set-Aside, NAICS Code 541519

JUST IN TIME: Yes

OFFER EXPIRATION DATE: Offers will be valid for 120 days unless a
different period is specified by the Offeror

To all Offerors: The purpose of this amendment is to respond to offerors' questions as follows:

- Q1. Attachment 1, *Statement of Work*, II, *Task VI*, states, in part; "Develop and test central database management system, including ... clinical site payment system." Please explain what is a/the clinical site payment system.
- A1. The clinical site payment system is the algorithms and mechanisms by which sites are reimbursed for their work under the contract/subcontract.
- Q2. Attachment 1, *Statement of Work*, II, *Task X*; states, in part: "Coordinate with pharmaceutical companies ... and coordinate/arrange for packaging, shipping, tracking, monitoring, and accountability of medication." Attachment 3 *Criteria*, 3, A, 1, c: cites, as one criterion in the evaluation; "distributing study drug." Is the

contractor expected to establish a drug distribution repository and distribution center, or coordinate and track distribution by the drug company to the clinical sites?

- A2. Most likely, the latter. But it may be that the contractor will have to arrange to coordinate with a drug packager/distributor who may not be the drug manufacturer.
- Q3. In Attachment 2, 2, A, 2: *Annual Technical Progress Reports*: Please clarify if six or three copies of the reports are to be submitted. If six, please state where the additional copies are to be sent.
- A3. Three (3) copies of the reports are to be submitted.
- Q4. Attachment 6, *Applicable Reference*, B. states, in part; "...SUBMIT WITH TECHNICAL PROPOSAL ... Technical Proposal Costs Information" Please explain what Technical Proposal Costs Information is to be included in the Technical Proposal.
- A4. Please reference the form found at the following web site for technical proposal cost information: <http://www4.od.nih.gov/ocm/contracts/rfps/techcst5.htm>
- Q5. Are outside contractors involved in the sample task given in the RFP in any capacity? And, are any contractors involved in the sample task prohibited to bid, or support anyone else in the bid on this RFP?
- A5. The sample task is presented to give idea of what a trials might look like and to give a basis for sites to use for budgeting estimates. It is not a trial that will be part of this contract. There are no incumbent contractors.
- Q6. Regarding the Q/A attachment provided in the previous amendment, in response #10, the Government states that a task order will be issued with the contract. Is this task the same as the sample task which we are to price with our proposal? If not, when would the Government issue the Statement of Work for the task so it could be awarded with the contract?
- A6. No, the sample task is for pricing comparison purposes only. NIMH expects to issue the first task order shortly after award of contract.
- Q7. In the previous amendment, NIMH stated that NIMH anticipates awarding all Task Orders on a Fixed-price basis. However the RFP states, on page 1 and in Attachment 4, M, (1) that a "cost-reimbursement" type contract is expected. Is this a modification to the RFP?
- A7. NIMH envisions awarding the contract with a ceiling amount and fix pricing each task order.

- Q8. In the amendment, NIMH indicated that pricing for the hypothetical Task Order should include pricing for all Tasks (including Task XV - Options.) Please indicate what options are to be priced.
- A8. Please disregard the requirement to price Task XV at this time.
- Q9. The Statement of Work refers to "clinical site payment." Will the contractor be required to contract with/pay the clinical sites?
- A9. Some tasks may ask the Contractor to subcontract with clinical sites, others will not.